USA COMMENTS

United States Comments on the BSE Code Chapter adopted during the 76th General Session (May 2008)

Chapter 2.3.13
Bovine Spongiform Encephalopathy

Introduction

Over the years the United States has supported the development of worldwide sanitary standards that are fair, feasible and grounded on sound science. Considering the important role of the OIE as an international standard setting body, it is critical that it continue to adhere to the use of science-based information upon which to base its recommendations.

It was evident that during the 76th General Session the International Committee did not take into consideration the science-based information proposed by the Terrestrial Animal Health Standards (Code) Commission to further update the *Code* pertaining to gelatin production. The end result from those deliberations is a 2008 *Code* version of Article 2.3.13.15 which is not only scientifically unjustifiable and more restrictive than previous standards for gelatin, but also inconsistent with Article 2.3.13.14 within the same chapter.

Specifically, the recently adopted language of Article 15 directly conflicts with the recommendations specified in Article 14, the article which identifies specified risk materials (SRM) by age and by BSE risk country classification. Article 14 states that brains, eyes, spinal cord, skull and vertebral column of cattle under the age of 30 months from controlled risk countries and of cattle under the age of 12 months from undetermined risk countries can be used to make food, feed, cosmetics, pharmaceuticals including biological materials and medical devices. Yet Article 15 (which immediately follows Article 14) and is specific to gelatin, a highly purified protein resulting from extensive processing, prohibits the use of bone from vertebrae from any animal regardless of age from either controlled or undetermined risk countries. Therefore, a material having less risk (vertebral column) and using a rigorous manufacturing process (acid or alkaline demineralization) cannot be used for gelatin, while brains and eyes from certain aged animals and with not specific processing restrictions can be used to make other products for animal and human consumption.

During several prior comment cycles, the United States has provided the OIE with scientific documentation to support the recommendation that bone gelatin should be traded freely without BSE related restrictions, i.e., bone gelatin should be included in the list of freely traded commodities in Article 2.3.13.1. However, while the United States continues to maintain this position, we also recognize that at the current time there is a lack of understanding among some countries about gelatin and how it is processed and made safe from BSE infectivity.

The United States is prepared to accept a compromised position for the time being so that the Code Commission can advance and correct the science in the 2008 Code. Restricting the use of certain bones (i.e., vertebral column and skulls from cattle over 12 months of age at time of slaughter) from undetermined risk countries should dissuade any further objections to the use of vertebrae in gelatin production.

Rationale and Scientific Justification for the proposed language of Article 2.3.13.15

As far back as March 2006, the Code Commission[1] recognized the safety of gelatin regardless of the country from which the bones for processing were obtained and regardless of the type (long bones versus vertebrae) of bone. Each year since then the Code Commission has been consistent in recommending that the OIE *Code* reflect the science surrounding the safety of gelatin.

With the above stated, the United States again reiterates the well referenced science documenting the safety of bone gelatin so that such science be utilized in the Code Commissions' proposal to reconcile the science and the *Code* standards for bone gelatin at the 77th General Session.

In 2006, the report by the scientific panel on biological hazards of the EFSA indicated that ". . . relative human exposures to BSE due to gelatin produced from bones including the skull and vertebral column sourced from cattle of any age are very low ($<10^{-5}$) and do not support the continuation of the restriction prohibiting the inclusion of skull and vertebral column."[2]

However, this report did state that the EFSA risk assessment did not consider the risk of sourcing bones from animals other than those deemed fit for human consumption and, therefore, those passing ante-mortem and post-mortem inspections. Further, this report indicated that to be consistent with the conservative approach adopted in respect of BSE, the commercial process for gelatin production must have been correctly carried out.

The United States believes these two restrictions to be neither appropriate nor needed to ensure the safe supply of gelatin. Extensive research conducted by highly respected, independent scientists and published in peer-reviewed research journals have demonstrated that the common commercial process of manufacturing bovine gelatin provides significant assurance of gelatin safety. Specifically, studies have shown that the current minimum processes which all manufacturers have in common (and that technically must be utilized to produce a marketable product) are more than sufficient to eliminate BSE infectivity from "worst case" artificially contaminated raw materials. This "worst case" infectivity of $10^{8.4}$ is far more than that found in raw materials sourced in

[1] Appendix XXVIII of the report of the meeting of the OIE Terrestrial Animal Health Standards commission 2-13 October 2006.
[2] European Food Safety Authority Journal 2006 312 (1-28).

the country which had the highest incidence of BSE at the height of the BSE epidemic.[3] [4] [5] Gelatin is a highly purified protein manufactured through various refining processes in which each step of processing is capable of significantly inactivating BSE infectivity if present.

Additionally, the New Zealand Food Safety Authority has proven through carefully conducted risk assessments the safety of gelatin beyond reasonable doubt regardless of the BSE status of source countries.[6] Given this document, the fact that the incidence of BSE cases is very much in decline and certainly the epidemic is well under control, and that the Code Commission is basing all decisions on science-based information, all gelatin should be freely traded regardless of the BSE risk status of the cattle population.

As a practical matter, the United States recognizes the reality of consumer perception and understands that countries need to ensure consumer confidence in their citizens' food supplies. We also recognize that the OIE prefers to take a conservative approach with respect to BSE. It is also evident from the International Committee deliberations at the most recent General Session that not all countries have a clear understanding of the unique and highly purifying processing required to manufacture bone gelatin. Accordingly, to allow gelatin to be traded unimpeded, and until education efforts enhance the understanding of gelatin processing, the raw materials used to make bone gelatin should be restricted as follows: gelatin originating from controlled BSE risk countries should exclude the skulls from cattle over 30 months of age and gelatin originating from undetermined risk countries should exclude skulls and the vertebrae (except tail vertebrae) from cattle over 12 months of age.

Recommended changes to 2008 edition of Article 2.3.13.15

The following recommended changes to the 2008 version of Article 2.3.13.15 reflect verbatim what was in the 2007 *Code* edition of Article 2.3.13. That is, the recommended changes to the 2008 *Code* are not new recommended standards, but are a reinstatement of

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[3] Grobben AH, Steele PJ, Somerville RA, Taylor DM (2004). Inactivation of the bovine spongiform encephalopathy (BSE) agent by the acid and alkaline processes used in the manufacture of bone gelatin. *Biotechnology and Applied Biochemistry,* 39; 329-338.

[4] Grobben AH, Steel PJ, Taylor DM, Somerville RA, Schreuder BEC (2005). Inactivation of the BSE agent by heat and pressure process for manufacturing gelatin. *Veterinary Record,* 157; 277-289.

[5] Grobben AH, Steele PH, Somerville RA, Taylor DM (2006). Inactivation of transmissible spongiform encephalopathy agents during the manufacture of dicalcium phosphate from bone. *Veterinary Record,* 158; 361-366.

[6] NZFSA (2005). Official's Review of New Zealand's BSE Country-Categorisation Measure. New Zealand Food Safety Authority, Wellington and published in "prions in Humans and Animals, Ed. By Hornlimann, Beat/ Riesner, Detlv / Kretzschmar, Hans. De Gruyter Veriag, Berlin (ISBN 978-3-11-018275-0).

prior standards which were science grounded, worked well and caused no negative health effects.

Article 2.3.13.15

Veterinary Authorities of *importing countries* should require:

for gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1. the *commodities* came from a country, *zone* or *compartment* posing a negligible BSE risk;

OR

2. they originate from a country, *zone* or *compartment* posing a controlled BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections; and that

   a) skulls from cattle over 30 months of age at the time of slaughter have been excluded ;

   b) the bones have been subjected to a process which includes all of the following steps:

      i) degreasing,

      ii) acid demineralisation,

      iii) acid or alkaline treatment,

      iv) filtration,

      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating)~~;~~.

3. they originate from a country, *zone* or *compartment* posing an undetermined BSE risk and are derived from cattle which have passed ante-mortem and post-mortem inspections, and that

   a) skulls and vertebrae (except tail vertebrae) from cattle over 12 months of age at the time of slaughter have been excluded;

   b) the bones have been subjected to a process which includes all of the following steps:

      i) pressure washing (degreasing)

      ii) acid demineralization,

      iii) acid or alkaline treatment,

      iv) filtration,

v) sterilization at ≥138°C for a minimum of 4 seconds,

or to an equivalent or better process in terms of infectivity reduction (such as high pressure heating)